

REMARKS

This responds to the Final Office Action dated October 7, 2010.

Claims 3 and 7 are amended, no claims are canceled, and no claims are added. Claims 1-46 remain pending in this application, with claims 24-38 withdrawn from consideration at this time.

Claim 3 is amended to clarify the recited subject matter. The amendment does not add new matter and is supported in the application as-filed, for example, at page 12, lines 6-31.

Claim 7 is amended to clarify the recited subject matter. The amendment does not add new matter and is supported in the application as-filed, such as at the base claim 1, as originally-filed.

Interview Summary

Appreciation is extended to Examiner Alyssa Alter for the courtesy of a helpful telephone interview on November 30, 2010 with Attorney Paul Kegley. Attorney Kegley called Examiner Alter to discuss the rejection of claim 7 under 35 U.S.C. 112. Examiner Alter requested that Attorney Kegley document his remarks in the present response to the present Office Action and indicated that those remarks would be given consideration. Agreement as to the withdrawal of the rejection was not reached during the interview.

The Rejection of Claims Under § 112

Claim 7 was rejected under 35 U.S.C. 112, second paragraph, for indefiniteness. Applicant respectfully traverses this rejection.

The Office asserts “[i]t is unclear if the Applicant has additional sensing circuitry to detect the T wave or how the T wave is sensed, since the intermediate claim 3 detects the “QRS complex” and a T-wave is not part of a “QRS complex”.” However, claim 7 merely recites, in part,

“the sensing circuit is configured such that an attenuation of a T-wave of the heart signal during the first time period is greater than or equal to the attenuation of the T-wave immediately after expiration of the first time period.”

Claim 7 does not refer to whether a T-wave is detected or sensed. Therefore, it is respectfully submitted that no uncertainty exists because claim 7 does not depend on whether or not there is additional sensing circuitry. Elements of claim 7 merely refer to a relationship of an attenuation of the recited sensing circuit during and after the first time period recited in claim 3. In responding to Applicant's previous remarks, the Office Action asserts:

The Applicant has argued that claim 7 is definite since the QRS complex and the T wave are both part of the heart signal. However, claim 7 depends on claim 3. *Claim 3 narrows the scope of the heart signal to the QRS complex. The sensing of the QRS complex excludes the T-wave (i.e., only Q-wave, R-wave, and S-wave).* Therefore, since claim 7 is dependent on claim 3, it is unclear how the T wave is determined.

(Office Action at 2 (emphasis added).) However, claim 3 does not even require that a QRS complex be sensed. Claim 3 merely recites a first time period that may be initiated by a QRS complex sensed by the first sensing circuit—however, claim 3 makes it clear that the first time period can also be initiated by a detected pacing therapy event, which can be a control signal that is generated in the system itself, rather than information sensed from the heart. Therefore, Applicant respectfully submits that the asserted premise that “Claim 3 narrows the scope of the heart signal to the QRS complex” is clear error.

Nonetheless, to expedite examination, Applicant has amended claim 7 to recite that the attenuation of the T-wave of the heart referred to in claim 7 is by the frequency response of the sensing circuit referred to in base claim 1 and intermediate claim 3. Reconsideration and withdrawal of the rejection, and allowance of claim 7 is respectfully requested.

The Rejection of Claims Under § 103

Claims 1-23 and 39-46 were rejected under 35 U.S.C. 103(a) over Seguine et al. (US Patent No. 6,185,450). Applicant respectfully traverses this rejection

The Office Action asserts that,

Seguine et al. discloses the claimed invention except for the range of time for the first time period. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the time period to restore the frequency response, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves routine skill in the art. *In re Aller*, 105 USPQ 233 (see MPEP 2144.05).

(Office Action at p. 5.) However, a careful review of the legal precedent relied upon by the Office Action makes clear that *In re Aller did not create a *per se* rule that a difference in range is never patentable*. Instead, the holding of *In re Aller* is limited to its very different facts: a chemical case in which the claimed process, which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was found obvious over a prior art process that differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%. *In re Aller*, 105 USPQ 233 (CCPA 1955). Under such extremely close differences in temperature and concentration, the court merely stated that:

Normally, it is to be expected that a change in temperature, or in concentration, or in both, would be an unpatentable modification. *Under some circumstances, however, changes such as these may impart patentability to a process if the particular range claimed produce a new and unexpected result which is different in kind and not merely in degree from the results of the prior art.*

In re Aller, 105 USPQ 233 (CCPA 1955) (emphasis added). Thus, the *In re Aller* court recognized that even a difference in concentration and temperature can—under appropriate facts—impart patentability. If the result is *different in kind*, and not merely different in degree from the results of the prior art, a finding of obviousness is clearly unsupportable under *In re Aller*.

The facts of the instant case are quite different from those in *In re Aller*. Here, there is not a mere difference in temperature and concentration of a chemical process. Instead, the present claimed subject matter can provide ECG sensing that provides good noise immunity after a paced or sensed QRS complex associated with a ventricular contraction, while still allowing appropriate sensing of a subsequent T-wave associated with an atrial contraction *during the same cardiac cycle*.

By contrast, Seguine's system is directed toward avoiding errors in marking QRS complexes in a system that is prone to saturation of its sense amplifiers. Seguine adjusts its frequency response slowly, over several cardiac cycles (see Seguine at FIG. 7A), and teaches that if the frequency response is adjusted more quickly, the amplifiers can re-saturate, yielding erroneously marked QRS complexes. (See Seguine at col. 7, lines 10-25.) Thus, Seguine *teaches away* from more quick adjustment of its frequency response,

and further expressly teaches that doing so will render Seguine unsuitable for its intended purpose of avoiding errors in marking QRS complexes.

Accordingly, Seguine's teachings provide irrefutable evidence that the time scale of Seguine's frequency adjustment is different in kind from the time scale of the presently claimed, which provides good noise immunity after a paced or sensed QRS complex associated with a ventricular contraction, while still allowing appropriate sensing of a subsequent T-wave associated with an atrial contraction during the same cardiac cycle. The present time scale is not only different in kind from the teachings of Seguine, they constitute unexpected results, in the sense that this particular result falls outside what one of ordinary skill in the art, using routine skill, would consider optimum for correctly detecting and marking the QRS according to Seguine.

In sum, consistent with *In Re Aller*, Applicant respectfully submits that claim 1 is novel and non-obvious over Seguine, because the recited elements of claim 1 provide new and unexpected results that are different in kind from Seguine, and not merely in degree, such as by providing a sensing circuit that is configured to restore the frequency response within a time period of less than or equal to 500 milliseconds such that the frequency response is restored during the same cardiac cycle as a detected event as recited in the claim.

Claims 2-21 depend either directly or indirectly on independent claim 1 and are believed to be in condition for allowance at least for the reasons discussed above with respect to claim 1. For brevity, Applicant defers but reserves the right to present further remarks concerning such dependent claims, which are additionally believed to be separately patentable.

AMENDMENT AND RESPONSE UNDER 37 C.F.R. § 1.116 - EXPEDITED PROCEDURE

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Filing Date: July 10, 2003

Title: CARDIAC RHYTHM MANAGEMENT SYSTEM WITH TIME-DEPENDENT FREQUENCY RESPONSE

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CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone the undersigned at (612) 373-6951 to facilitate prosecution of this application.

If necessary, please charge any additional fees or deficiencies, or credit any overpayments to Deposit Account No. 19-0743.

Respectfully submitted,

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